

Application No.: 10/609,233
Amendment Dated October 6, 2008
Reply to Office Action of October 17, 2006

Amendments to the Claims:

1. (Currently Amended) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising about ~~0.1~~ 0.001 mg/ml to about ~~15~~ 0.50 mg/ml of a hypertension reducing agent, wherein said formulation is suitable for local administration to the lungs of a mammal such that a systemic effect is circumvented and said pulmonary hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator and wherein said formulation is suitable for administration via inhalation to a mammal in need thereof, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.

2. (Previously Presented) The formulation of claim 1, wherein said formulation is suitable for local administration to the lungs of a mammal by oral inhalation via nebulization.

3-11. (Canceled)

12. (Original) The formulation of claim 2, wherein said formulation is an aqueous suspension.

13. (Original) The formulation of claim 12, wherein said suspension is sterile.

14. (Original) The formulation of claim 13, wherein said suspension comprises an emulsifier.

15. (Previously Presented) The formulation of claim 14, further comprising at least one complexing agent including sodium edetate.

16. (Original) The formulation of claim 2, wherein said formulation comprises a preservative.

17-20. (Canceled)

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21. (Original) The formulation of claim 2, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

22-24. (Canceled)

25. (Original) The formulation of claim 2, wherein said formulation is suitable for treating primary pulmonary hypertension.

26. (Original) The formulation of claim 2, wherein said formulation is suitable for treating secondary pulmonary hypertension.

27. (Currently Amended) A method of treating pulmonary hypertension in a mammal, said method comprising the step of locally administering to the lungs of said mammal a formulation comprising about 0.1 0.001 mg/ml to about 15 0.50 mg/ml of a hypertension reducing agent such that a systemic effect is circumvented and at least one complexing agent, wherein said hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator, and wherein said formulation is suitable for administration via inhalation, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.

28. (Previously Presented) The method of claim 27, wherein said formulation is locally administered to the lungs of said mammal by oral inhalation via nebulization to said mammal.

29. (Original) The method of claim 28, wherein said formulation is administered via jet nebulizer, ultrasonic nebulizer or breath-actuated nebulizer to said mammal.

30. (Original) The method of claim 27, wherein said formulation is premeasured, premixed and prepackaged.

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31. (Canceled)

32. (Original) The method of claim 31, wherein said formulation is sterile and stable.

33. (Canceled)

34. (Original) The method of claim 27, said method further comprising the step of administering to said mammal an inotropic agent.

35-37. (Canceled)

38. (Currently Amended) A kit for treating pulmonary hypertension in a mammal, said kit comprising an prepackaged formulation comprising about 0.1 0.001 mg/ml to about 15 0.50 mg/ml of a hypertension reducing agent and at least one complexing agent, wherein said formulation is suitable for local administration to the lungs of a mammal such that a systemic effect is circumvented and said hypertension reducing agent is at least one of an ACEI, ARB, beta-blocker, calcium-channel blocker or vasodilator, and wherein said formulation is suitable for administration via nebulization to a mammal in need thereof, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.

39. (Original) The kit of claim 38, wherein said formulation is prepackaged.

40. (Original) The kit of claim 38, further comprising instructions relating to said formulation.

41-50. (Canceled)

51. (Currently Amended) An inhalable formulation for the treatment of pulmonary hypertension, said formulation comprising an aqueous suspension having about 0.1 0.001 mg/ml to about 15 0.50 mg/ml of a calcium-channel blocker and at least one complexing agent selected from the group consisting of ethylenediaminetetraacetic acid, citric acid, nitrilotriacetic acid,

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sodium edetate and salts thereof; wherein said formulation is suitable for local administration to the lungs of a mammal such that a systemic effect is circumvented and said formulation is suitable for administration via inhalation to a mammal in need thereof, wherein the formulation is not a liposomal formulation and is free of a compound selected from the group consisting essentially of (i) an anti-EMAP II antibody; (ii) antisense EMAP II oligonucleotide; and (iii) EMAP II antagonist; wherein said formulation is isotonic and has a pH of about 3 to about 8.

52. (Previously Presented) The inhalable formulation according to claim 51, wherein said calcium-channel blocker includes at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

53. (Currently Amended) The inhalable formulation according to claim 51, ~~wherein the formulation comprises from about .001 to 10 mg/ml of said calcium-channel blocker and further comprising~~ from about 0.01% to 90% of a suspending agent.

54. (Previously Presented) The inhalable formulation according to claim 53, wherein said suspending agent comprises water, alcohol, glycol, aqueous saline solution, and combinations thereof.

55. (Canceled)

56. (Canceled)

57. (Previously Presented) The inhalable formulation according to claim 51, wherein said formulation is premeasured, premixed and prepackaged.

58. (Previously Presented) The inhalable formulation according to claim 51, wherein said suspension includes at least one buffer selected from the group consisting of sodium hydroxide, sodium citrate and citric acid.

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59. (Previously Presented) The inhalable formulation according to claim 51, wherein said formulations is disposed in a dispensing container that is configured to deliver said formulation via nebulization.

60. (Previously Presented) The inhalable formulation according to claim 59, wherein said dispensing container is capable of delivering a single unit dose of a therapeutically effective amount of said calcium-channel blocker.

61. (Previously Presented) The method of claim 27, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

62. (Previously Presented) The method of claim 27, wherein said formulation comprises from about 0.001 to 10 mg/ml of said calcium-channel blocker and from about 0.01% to 90% of a suspending agent.

63. (Previously Presented) The method of claim 62, wherein said suspending agent comprises water, alcohol, glycol, aqueous saline solution, and combinations thereof.

64. (Previously Presented) The method of claim 62, wherein said formulation comprises from about 0.01 mg/ml to 10 mg/ml of said calcium-channel blocker.

65. (Canceled)

66. (Previously Presented) The kit of claim 38, wherein said calcium-channel blocker is at least one of the group consisting of amlodipine, bepridil, diltiazem, felodipine, flunarizine, isradipine, nicardipine, nifedipine, nimodipine and verapamil.

67. (Previously Presented) The kit of claim 38, wherein said formulation is prepackaged in a dispensing container that is configured to deliver a single unit dose of a therapeutically effective amount of said calcium-channel blocker via nebulization.

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68. (Previously Presented) The kit of claim 67, wherein said dispensing container is prefilled with about 0.1 to 5.0 ml of said formulation.

69. (Previously Presented) The kit of claim 67, wherein said formulation is administered via jet nebulizer, ultrasonic nebulizer or breath-actuated nebulizer to said mammal.

70. (New) The formulation of claim 1, further comprising from about 0.001% to about 10% of an agent selected from sodium alginate, potassium alginate, ammonium alginate, calcium alginate, or propane-1,2-diol alginate.

71. (New) The method of claim 27, wherein the formulation further comprises from about 0.001% to about 10% of a lecithin.